REMARKS

This Amendment and Response is submitted in response to the Office Action mailed 29 JULY 2002. Withdrawal of the rejection and reconsideration with an eye toward allowance is respectfully requested.

Claim Status

Claims 1-5, 8-18, 20-30, 34, 47-44, 49-61, 64-68, 74 and 75 are pending after entry of the present amendment. Claims 1-5, 8-18, 20-30, 34, 47-44, 49-61, 64-68, 74 and 75 stand rejected. Claims 34 and 44 are amended herein to conform to proper Markush group form. A complete listing of all claims that are, or were in the application, along with an appropriate status identifier, is provided above in the section entitled "Amendments to the Claims". Markings are provided on claims amended in the present amendment.

Claim Rejections – 35 U.S.C. §112

Claims 34 and 44 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner notes that it is improper to use the term "comprises" in a Markush claim. Applicant has amended claims 34 and 44 and trusts that the amendments free the claims from the 35 U.S.C. §112 rejection.

Claim Rejections –35 U.S.C. §102

Claims 64-68 were rejected under 35 U.S.C. §102(b) as being anticipated by Cozzette et. al. (U.S. Patent Number 5,200,051).

Cozzette is generally directed to an efficient method for the microfabrication of electronic devices which have been adapted for the analysis of biologically significant analyte species (see Abstract). In particular, Cozzette describes a glucose sensor unit cell. The unit cell includes a catalytic indicator electrode surrounded by a combined reference and counter electrode (see Cozzette, col. 24, lines 22-29 and FIG. 1).

In contrast, Applicant's claim 64 recites "selecting a first input electrode in contact with a plurality of test sites including said specific test site" and "selecting a first output electrode in contact with a plurality of test sites including said specific test site".

As the Examiner is aware, for a reference to anticipate a claim, the reference must teach every element of the claim (see M.P.E.P §2131).

Applicant respectfully submits that Cozzette fails to disclose all limitations of Applicant's independent claim 64, including "selecting a first input electrode in contact with a plurality of test sites

including said specific test site" and "selecting a first output electrode in contact with a plurality of test sites including said specific test site". Cozzette discloses that each unit sensor cell includes two electrodes. There is no disclosure in Cozzette of selecting an input electrode in contact with a plurality of test sites, or selecting an output electrode in contact with a plurality of test sites. Each test site disclosed by Cozzette includes two independent electrodes which are not in electrical communication with other test sites.

Claims 65-68 depend from and include all limitations of Applicant's independent claim 64. Accordingly, Applicant submits that the 35 U.S.C. §102(b) rejection of claims 64-66 over Cozzette is improper and should be withdrawn.

Further, Applicant's dependent claims 65-68 further recite particular limitations on electrical or electrochemical detection methods. The Examiner states that "the type of electrical or electrochemical detection of claims 65-68 would be a choice as experimental design and is considered within the purview of the prior art" (see office action, page 5). The Examiner's attention is respectfully drawn to M.P.E.P. §2131.01. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim" *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Accordingly, Applicant submits that the further limitations recited in claims 65-68 are not specifically disclosed by Cozzette, making the 35 U.S.C. §102(b) rejection over Cozzette improper.

Claim Rejections –35 U.S.C. §103

Claims 64 and 74-75 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cozzette and Ishikawa (U.S. Patent Number 3,619,511).

Cozzette is discussed above.

Ishikawa discloses an electrical circuit, including a multiplexor and de-multiplexor, for operating upon a number of input signals that may be subject to widely varying magnitudes, to provide an optimum magnitude of all of the signals and at the same time retain the relative signal values and an indication of the absolute signal value. It is important to note that Ishikawa is entitled "Data Normalization Apparatus" and that a key component of the Ishikawa system for data handling, in addition to a multiplexor, is a single gain control amplifier for normalizing the signals.

In contrast, Applicant's claim 64 recites "selecting a first input electrode in contact with a plurality of test sites including said specific test site" and "selecting a first output electrode in contact with a plurality of test sites including said specific test site".

Applicant notes that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Further, the reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. §2142).

The Examiner suggests it would be obvious to include a multiplexor as taught by Ishikawa in the apparatus of Kayyem (see office action, page 7). For purposes of response, Applicant has assumed that the Examiner intended to write "..in the apparatus of Cozzette" in paragraph 2 on page 7 of the office action, which would be consistent with the rejection over Cozzette in view of Ishikawa. Applicant respectfully submits that the Examiner has not demonstrated the necessary suggestion or motivation to modify Cozzette with Ishikawa. The Examiner suggests that the motivation would be for the advantage of providing a data processing system that can handle or transmit a number of signals of widely varying range (office action, page 7). Applicant respectfully submits that identifying a described advantage of the system of Ishikawa (the ability to operate on a number of input signals subject to widely varying magnitudes), does not itself provide motivation to combine that teaching with that of a glucose sensor unit cell, as taught by Cozzette. Further, Applicant submits that "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what reference fairly suggests to one of ordinary skill in the art". *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965). "It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 USPQ2d 1780, 1784 (CAFC 1992). In the present application, Applicant respectfully submits that the Examiner has impermissably pieced together the multiplexor contained in the disclosure of Ishikawa with the system of Cozzette. As noted above, Ishikawa requires more than the multiplexor to accomplish a data handling or data processing system. Applicant respectfully submits that the Ishikawa reference, taken as a whole, is directed to a circuit for operating upon input signals subject to widely varying magnitudes. This circuit contains, among other required elements, a multiplexor. Applicant respectfully submits that there is no suggestion to remove the multiplexor from the circuit disclosed by Ishikawa and apply the multiplexor to the biosensor disclosed by Cozzette. In fact, as noted above, the Ishikawa system requires additional components to accomplish the goal of processing a larger number of signals. Accordingly, Applicant submits that the proper motivation to combine the references is not present, and the 35 U.S.C. §103 rejection over Cozzette in view of Ishikawa is improper.

Further, Applicant submits that the references, taken alone or in combination, fail to disclose or suggest all limitations of Applicant's claim 64. As discussed above, Applicant submits that Cozzette fails to disclose all limitations of Applicant's claim 64 including "selecting a first input electrode in contact with a plurality of test sites including said specific test site" and "selecting a first output electrode in contact with a plurality of test sites including said specific test site". Applicant further submits that Ishikawa is silent as to this feature, the Ishikawa reference being directed completely to an electronic circuit, and containing no disclosure of a plurality of test sites having a probe molecule bound thereto. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection over Cozzette in view of Ishikawa is improper.

Claims 74-75 depend from and include all limitations of Applicant's independent claim 64. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection of claims 64 and 74-75 over Cozzette in view of Ishikawa should be withdrawn.

Claims 1-2, 5, 8-18, 20-30, 34, 37-44, and 49-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cozzette and Ishikawa.

Cozzette and Ishikawa are discussed above.

In contrast, Applicant's independent claims 1 and 2 recite "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites;".

As stated above, Applicant notes that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Further, the reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. §2142).

As stated above with regard to the rejection of claims 64 and 74-75 over Cozzette and Ishikawa, Applicant respectfully submits that the necessary motivation to combine the references is lacking. The Examiner states that it would be obvious to include a multiplexor as taught by Ishikawa in the apparatus of Kayyem (see office action, page 9). Again, for the purposes of response, Applicant has assumed the Examiner intended to write "... in the apparatus of Cozzette", consistent with the rejection over Cozzette in view of Ishikawa. The Examiner states that the motivation would be for the advantage of provided a data processing system that can handle or transmit a number of signals of widely varying range. As stated above, Applicant submits that the identification of an advantage of the system of Ishikawa is not equivalent to a motivation to combine that teaching with the biosensor of Cozzette. Further, as argued above, Applicant submits that the Examiner has impermissably picked an element out of the Ishikawa teaching to arrive at the subject matter of Applicant's claim. This argument is incorporated again here by reference.

Further, Applicant submits that Cozzette and Ishikawa, taken alone or in combination, fail to disclose or suggest all limitations of Applicant's independent claims 1 and 2 including a set of input electrodes, each in contact with a plurality of test sites and a set of output electrodes, each in contact with a plurality of test sites.

Claims 5, 8-18, 20-30, 34, 37-44, and 49-61 depend from and include all limitations of Applicant's independent claims 1 or 2. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection of claims 1, 2, 5, 8-18, 20-30, 34, 37-44, and 49-61 is improper and should be withdrawn.

Claims 3-4 were rejected under 35 U.S.C. §103(a) over Cozzette and Ishikawa and further in view of Roberts (U.S. Patent No. 5,958,791).

Cozzette and Ishikawa are discussed above.

Roberts discloses a test device having interdigitated electrodes. The device relies on electrochemical detection of an electroactive marker (see col. 9, lines 36-37 and col. 21, lines 36-38). A test strip is placed in a solution, and as the solution traverses the absorbent strip, electroactive markers may be released that traverse a set of interdigitated electrodes (see FIG. 1 and col. 15, lines 45-66). A set of interdigitated electrodes is provided that traverses a single test strip (see FIG. 1).

In contrast, Applicant's claims 3-4 depend from and include all limitations of Applicant's independent claims 1 and 2, which recite "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites;".

As stated above, Applicant notes that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Further, the reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. §2142).

As stated above, and incorporated here by reference, Applicant submits that the necessary motivation to combine the references Cozzette and Ishikawa is lacking. As to the addition of the Roberts reference, the Examiner provides a motivation to combine the interdigitated electrodes taught by Roberts into the apparatus of Kayyem in view of Ishikawa (see office action, page 10). Again, for purposes of response, Applicant has assumed the Examiner intended to state that the motivation was to combine the electrodes taught by Roberts into the apparatus of Cozzette in view of Ishikawa, consistent with the rejection. The Examiner states the motivation would be for the advantage of increasing signal detection such as increasing signal-to-noise ratio and decreasing ohmic signal losses. However, Applicants submit that this is a legally incorrect determination of motivation. The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F 2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). There is no suggestion in either reference of modifying or combining the references to reach the claims of the present invention. That is, while Roberts describes interdigitated electrodes, all references – alone or in combination – fail to suggest or motivate the use of interdigitated electrodes in an apparatus having a set of input electrodes, each in contact with a plurality of test sites, and a set of output electrodes, each in contact with a plurality of test sites, as recited in Applicants' claims 1 and 2. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection is improper.

Further, Applicant submits that the references, taken alone or in combination, fail to disclose or suggest all limitations of Applicant's claims 1 and 2, including "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites;". As discussed above, Applicant submits that neither Cozzette nor Ishikawa disclose these features. Applicant further submits that Roberts does not disclose these features. Claims 3 and 4

depend from and include all limitations of Applicant's claims 1 and 2. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection of claims 3 and 4 over Cozzette and Ishikawa in view of Roberts is improper and should be withdrawn.

Claims 1-2, 5, 8-18, 20-30, 34, 37-44, and 49-61 were rejected under 35 U.S.C.§103(a) as being unpatentable over Kayyem et. al (U.S. Patent Number 6,290,839) and Ishikawa.

Kayyem discloses an apparatus for detection of analytes comprising two sets of electrodes – an electrophoresis set and a detection set (see Kayyem Figs. 1A-F and col. 2, lines 40-42). Each detection electrode corresponds to a test site. Assay complexes generated by Kayyem include electron transfer moieties (see col. 6, lines 18-20).

Ishikawa is discussed above.

In contrast, claims 1 and 2 recite "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites;".

As stated above, Applicant notes that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Further, the reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. §2142).

First, Applicant respectfully submits that the Examiner has not provided an appropriate motivation to combine the references. The Examiner suggests that the motivation would be for the advantage of providing a data processing system that can handle or transmit a number of signals of a widely varying range. Applicant respectfully submits that identifying a described advantage of the system of Ishikawa (the ability to operate on a number of input signals subject to widely varying magnitudes), does not itself provide motivation to combine that teaching with that of an apparatus for detection of analytes, as taught by Kayyem. Further, Applicant submits that "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what reference fairly suggests to one of ordinary skill in the art". *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965). "It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 USPQ2d 1780, 1784 (CAFC 1992). In the present application, Applicant respectfully submits that the Examiner has impermissably pieced together the multiplexor contained in the disclosure of Ishikawa with the system of Kayyem. Applicant respectfully submits that the Ishikawa reference, taken as a whole, is directed to a circuit for operating upon input signals subject to widely varying magnitudes. This circuit contains, among other required elements, a multiplexor. Applicant respectfully submits that there is no suggestion to remove the multiplexor from the circuit disclosed by Ishikawa and apply the multiplexor to the system disclosed by Kayyem. In fact, as noted above, the Ishikawa system requires additional components to accomplish the goal of processing a

larger number of signals. Accordingly, Applicant submits that the proper motivation to combine the references is not present, and the 35 U.S.C. §103 rejection over Kayyem in view of Ishikawa is improper.

Further, Applicant submits that the references, alone or in combination, fail to disclose all limitations of Applicant's claims 1 and 2 including "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites". Kayyem is silent as to a set of input electrodes, where each electrode is in contact with a plurality of test sites, and a set of output electrodes, where each electrode is in contact with a plurality of test sites. Ishikawa is further silent as to these features. Claims 5, 8-18, 20-30, 34, 37-44, and 49-61 depend from and include all limitations of Applicant's claims 1 and 2. Accordingly, Applicants submit that the 35 U.S.C. §103(a) rejection of claims 1, 2, 5, 8-18, 20-30, 34, 37-44, and 49-61 over Kayyem in view of Ishikawa is improper and should be withdrawn.

Claims 3-4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kayyem et al. and Ishikawa in further view of Roberts.

Kayyem, Ishikawa, and Roberts are discussed above.

In contrast, Applicant's claims 3 and 4 depend from and include all limitations of Applicant's claims 1 and 2 including "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites".

As stated above, Applicant notes that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Further, the reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. §2142).

First, Applicant submits that the Examiner has not provided a proper motivation to combine the references. The lack of motivation to combine the references of Kayyem and Ishikawa is discussed above and incorporated again here by reference. With regard to the further combination of Roberts, the Examiner suggests that the motivation would be for the advantage of increasing signal detection such as increasing signal-to-noise ratio and decreasing ohmic signal losses. However, Applicants submit that this is a legally incorrect determination of motivation. The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F 2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). There is no suggestion in either reference of modifying or combining the references to reach the claims of the present invention. That is, while Roberts describes interdigitated electrodes, all references – alone or in combination – fail to suggest or motivate the use of interdigitated electrodes in an apparatus having a set of input electrodes, each is in contact with a plurality of test sites, and a set of output electrodes, each in

contact with a plurality of test sites, as recited in Applicants' claims 1 and 2. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection is improper.

Further, Applicant submits that the references, taken alone or in combination fail to disclose all limitations of Applicant's claims 1 and 2 including "a supporting substrate comprising an array of test sites, a set of input electrodes, each in contact with a plurality of test sites, a multiplexor connected to the set of input electrodes;" and "a set of output electrodes, each in contact with a plurality of test sites". Kayyem's and Ishikawa's silence as to these features is discussed above. Roberts is further silent as to these features, as is also discussed above with regard to the 35 U.S.C. §103 rejection over Cozzette, Ishikawa and Roberts. Applicant's claims 3 and 4 depend from and include all limitations of Applicant's claims 1 and 2. Accordingly, Applicant submits that the 35 U.S.C. §103(a) rejection of claims 3-4 over Kayyem in view of Ishikawa in further view of Roberts is improper and should be withdrawn.

CONCLUSION

Applicants submit the claims are in condition for allowance, and notification of such is respectfully requested. If after review, the Examiner feels there are further unresolved issues, the Examiner is invited to call the undersigned at (415) 781-1989. While Applicant believes that no further fees are due at this time, the Commissioner is authorized to charge any fees that may be due as a result of filing this amendment, including additional claims fees not already paid for, or other fees that have not been separately paid, to Deposit Account 50-2319 (Order No. 469008-137 [A-70203/RMS/RMK/JML]).

Respectfully submitted,
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Filed under 37 C.F.R. §1.34(a)

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